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Department of Health and Human Services

Office of the Secretary

Privacy Act of 1974; System of Records Notice

AGENCY: Department of Health and Human Services (HHS), Office of the Secretary (OS)

ACTION: Notice to establish a new system of records, and to delete related systems.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is establishing a new, department-wide system of records, System No. 09-90-1601 "Outside Experts Recruited for Non-FACA Activities," and deleting four related systems of records that are obsolete or that will be rendered duplicative by the new system. The new system will cover recruitment and other administrative records about individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees and other assignments requiring specific outside expertise or experience (excluding those that are subject to the Federal Advisory Committee Act (FACA), which are covered under System No. 09-90-0059). The new department-wide System No. 09-90-1601 and the related system deletions are more fully explained in the "Supplementary Information" section of this Notice.

DATES: The new system of records established in this Notice is effective upon publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication of this Notice, unless comments are received that warrant a revision to this Notice. Written comments on the Notice should be submitted within 30 days. The deletion of System Numbers 09-20-0168, 09-30-0049, 09-37-0022, and 09-90-0080 will be effective 30 days after publication of this Notice.

ADDRESSES: The public should address written comments to: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building – Suite 729H, 200 Independence Avenue, SW, Washington, DC 20201, beth.kramer@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building – Suite 729H, 200 Independence Avenue, SW, Washington, DC 20201, beth.kramer@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Explanation of New System No. 09-90-1601

The records to be covered in the new system of records are similar in type and function to the records covered in System No. 09-90-0059, which pertain to individuals who serve or are considered for service on committees that are subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., et seq.; the key difference is that they will be about outside individuals serving or considered for service on mission-related committees and other activities that are not subject to FACA. Following are the non-FACA-related programs at HHS that recruit and utilize

individuals with outside expertise or experience and maintain records about the outside individuals in systems that retrieve the records by personal identifier:

- Centers for Disease Control and Prevention (CDC) (formerly covered under SORN 09-20-0168).

 This program maintains records about individuals with special expertise, training, and professional experience who may be enlisted to assist CDC/NCHS as consultants. The records are used by CDC/NCHS to select individuals to participate in assignments such as: planning and conducting surveys, studies, statistical reporting programs, and statistical analyses of data; providing training and technical assistance; and planning and conducting conferences. These records currently are covered under SORN No. 09-20-0168, which is being deleted and subsumed under the new department-wide SORN No. 09-90-1601.
- The Food and Drug Administration (FDA) Patient Representative Program. This program enlists individuals with patient advocacy experience to serve as patient representatives on both FACA committees and non-FACA assignments. For example, patient representatives may provide input that is used in making decisions to approve devices or drugs, or may contribute to discussions at presentations and conferences. Records about patient representatives are retrieved by the representatives' names, and will be covered under either SORN No. 09-90-0059 or the new department-wide SORN No. 09-90-1601, depending on whether the records pertain to service on a FACA committee or service on a non-FACA assignment.
- Peer Review Programs at the Administration for Children and Families (ACF), Health Resources
 and Services Administration (HRSA), and Substance Abuse and Mental Health Services

 Administration (SAMHSA) that recruit and use outside individuals to serve on peer review
 committees formed to review applications for grants and cooperative agreements. These

programs exist in several HHS components, but only ACF, HRSA, and SAMHSA sometimes use a personal identifier (i.e., name) to retrieve administrative records about the outside individuals they recruit and use. Other components (including the Office of the Assistant Secretary for Health (OASH), Centers for Medicare & Medicaid Services (CMS), and National Institutes of Health (NIH)) use only non-personal identifiers (e.g., expertise type, or funding opportunity announcement number) for retrieval.

Consultants on Other SAMHSA Projects (formerly covered under SORN 09-30-0049). SAMHSA
contractors arrange for outside consultants to be used in other SAMHSA programs (besides peer
review programs) when technical assistance is needed in conferences, meetings, and evaluation
projects that involve a specialized area of research, review, or advice.

A report on the new system of records has been sent to Congress and OMB in accordance with 5 U.S.C. 552a(r).

II. Deletion of Four Related Systems of Records

The following systems of records are being deleted as duplicative of new department-wide System No. 09-90-1601:

- 09-20-0168 Curricula Vitae of Consultants to the National Center for Health Statistics
- 09-30-0049 Consultant Records Maintained by SAMHSA Contractors

The following system of records is being deleted as duplicative of System No. 09-90-0059

Federal Advisory Committee Membership Files as to files that pertain to candidates for FACA committees, and as duplicative of new department-wide System No. 09-90-1601 as to files that pertain to candidates for non-FACA committees and other activities:

09-90-0080 The Secretary's Advisory Committee Candidate Files

The following system of records is being deleted because it is obsolete and the records no longer

exist:

9-37-0022 Records of Health Experts Maintained by the Office of International Health

III. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the U.S. Government collects,

maintains, and uses information about individuals in a system of records. A "system of records"

is a group of any records under the control of a federal agency from which information about an

individual is retrieved by the individual's name or other personal identifier. The Privacy Act

requires each agency to publish in the Federal Register a system of records notice (SORN)

identifying and describing each system of records the agency maintains, including the purposes

for which the agency uses information about individuals in the system, the routine uses for which

the agency discloses such information outside the agency, and how individual record subjects

can exercise their rights under the Privacy Act.

Dated: November 1, 2016.

Beth Kramer, Privacy Act Officer FOIA/Privacy Act Division Assistant Secretary for Public Affairs Department of Health and Human Services NOTICE OF DELETION OF RELATED SYSTEMS:

The following systems of record are deleted, effective 30 days after publication of this Notice:

1. 09-20-0168 Curricula Vitae of Consultants to the National Center for Health Statistics

2. 09-30-0049 Consultant Records Maintained by SAMHSA Contractors

3. 09-90-0080 The Secretary's Advisory Committee Candidate Files

4. 09-37-0022 Records of Health Experts Maintained by the Office of International Health

SYSTEM NUMBER: 09-90-1601

SYSTEM NAME: Outside Experts Recruited for Non-FACA Activities

SECURITY CLASSIFICATION: Unclassified.

SYSTEM LOCATION: Physical locations include:

 CDC program offices that recruit consultants to assist in statistical projects and reporting programs conducted or sponsored by NCHS, in Atlanta, GA and Hyattsville, MD;

• FDA's committee management office in Silver Spring, MD;

Program offices at ACF in Washington, DC, at HRSA in Rockville, MD, and at SAMHSA in

Rockville, MD, that recruit individuals to serve as peer reviewers; and

Locations of SAMHSA contractors that arrange use of consultants on SAMHSA projects.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM: Records in this system pertain to individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees or other assignments that require specific outside expertise or experience (for example, medical, scientific, or manufacturing expertise, or patient advocacy experience), but that are not subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., et seq.

CATEGORIES OF RECORDS IN THE SYSTEM: The records consist of recruitment and other administrative records, including:

- An application and resume or curricula vitae, describing the individual's qualifications;
- Nomination/recommendation records, or other records used in evaluating an individual's
 qualifications and any potential conflicts of interest and selecting an individual for a specific
 assignment; and
- Records used to plan and arrange the individual's participation in the assigned activities,
 including scheduling records and records used to coordinate parking, badging, and payment of any stipend or honorarium.

The records may contain these data elements:

- The individual's name and other identifying information (e.g., sex, place and date of birth);
- Contact information (e.g., home and business addresses, telephone numbers, email addresses);

Occupation, job titles, employers, employment status and history, and whether currently

employed by the federal government;

Work and organizational affiliations, memberships, credentials, and licenses;

Degrees held, and general educational and/or experience background;

Racial classification or ethnic background;

Areas of specialization, expertise, or experience, and special qualifications (e.g., language or

technical skills, ability to drive to an assignment);

Dates and descriptions of past assignments or past experience;

Sources and references, and any information provided by sources/references; and

Information about availability and any special needs.

Any special needs, medical condition, or similar information contained in an individual's records

is maintained and used in accordance with relevant provisions of the Rehabilitation Act of 1973,

as amended, 29 USC 791 et seq., and implementing regulations at 29 CFR parts 1614 and 1630,

and the Genetic Information Nondiscrimination Act of 2008 at 42 USC 2000ff et seq.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

For CDC/NCHS Consultant Records: 42 U.S.C. 242b(b)(3)

For FDA Patient Representative Records: 21 U.S.C. 360bbb-8c, 371 et seq., 379d-1(b)(1)(A)

For ACF Peer Reviewer Records: 42 U.S.C. 799(f), 806(e)

For HRSA Peer Reviewer Records: 42 U.S.C. 799(f), 806(e)

For SAMHSA Peer Reviewer and Other Consultant Records: 42 U.S.C. 241, 249(c), 290aa et

seq., 290aa-5, 290bb et seq., 290bb-21 et seq., 290bb-31 et seq., 5121 et seq., 10801 et seq.; 8

U.S.C. 1522 note; Executive Order 12341

See also: 5 USC 3109

PURPOSE(S): The records will be used within the agency on a need-to-know basis for the

purpose of staffing committees and other assignments and managing administrative matters

pertaining to individuals serving on committees and other assignments, including to:

Prepare reports and lists of past, present, and recommended members, vacancies, acceptances,

and separations;

Send recruitment notices to individual prospective candidates, and send informational notices

to selectees;

• Identify qualified candidates and document the selections; and

Manage and coordinate the selected individuals' participation in assignment activities (including

sharing information within the agency to coordinate aspects such as badging, parking, travel,

training, and payment of any stipend or honorarium).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING

CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES: In addition to the

statutory disclosures of information permitted in the Privacy Act at 5 U.S.C. 552a(b)(2) and

(b)(4)-(11), HHS may make the following disclosures of information about an individual from

this system of records to parties outside the agency without the individual's prior, written consent:

- Disclosures may be made to federal agencies and Department contractors that have been
 engaged by HHS to assist in accomplishment of an HHS function relating to the purposes of this
 system of records and that have a need to have access to the records in order to assist HHS in
 performing the activity. Any contractor will be required to comply with the requirements of the
 Privacy Act.
- Records may be disclosed to parties such as educational institutions, current and former employers, and qualified experts, when necessary to check or obtain an opinion about a candidate's qualifications.
- 3. Records about consultants and patient advocates may be disclosed to parties organizing or hosting assignment activities, such as grantee institutions and federal, foreign, state, tribal, local, and other government agencies and public authorities (e.g., U.S. Embassies and Ministries of Health), when necessary to apprise them of an individual's qualifications for the assignment or coordinate the individual's participation in the activities.
- 4. Records may be disclosed to supervisors and administrative assistants at the individual's place of employment, for administrative purposes such as coordinating the individual's participation in the activities.
- 5. Records may be disclosed to external parties that audit committee or assignment activities.
- 6. Relevant information will be included in any required reports to the President, the Office of Management and Budget (OMB), and the General Services Administration (GSA) about committees and other assignments that are mission-related.

- 7. Information may be disclosed to the U.S. Department of Justice (DOJ) or to a court or other tribunal, when:
 - a. The agency or any component thereof, or
 - b. Any employee of the agency in his or her official capacity, or
 - c. Any employee of the agency in his or her individual capacity where DOJ has agreed to represent the employee, or
 - d. The United States Government,

is a party to litigation or has an interest in such litigation and, by careful review, HHS determines that the records are both relevant and necessary to the litigation and that, therefore, the use of such records by the DOJ, court or other tribunal is deemed by HHS to be compatible with the purpose for which the agency collected the records.

- 8. Records may be disclosed to student volunteers and other individuals performing functions for the Department but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.
- Disclosures may be made to the National Archives and Records Administration (NARA) and/or the General Services Administration (GSA) for the purpose of records management inspections conducted under 44 U.S.C. 2904 and 2906.
- 10. Information may be disclosed to a Member of Congress or a Congressional staff member in response to a written inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained. The Congressional office does not have any

greater authority to obtain records than the individual would have if requesting the records

directly.

11. Records may be disclosed to the U.S. Department of Homeland Security (DHS) if captured in an

intrusion detection system used by HHS and DHS pursuant to a DHS cybersecurity program that

monitors Internet traffic to and from federal government computer networks to prevent a

variety of types of cybersecurity incidents.

12. Disclosures may be made to appropriate federal agencies and Department contractors that have

a need to know the information for the purpose of assisting the Department's efforts to respond

to a suspected or confirmed breach of the security or confidentiality of information maintained

in this system of records, when the information disclosed is relevant and necessary to that

assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING,

RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM--

STORAGE: Records are stored in hard-copy files and electronic media.

RETRIEVABILITY: Records are retrieved by the individual's name.

SAFEGUARDS: Safeguards conform to the HHS Information Security and Privacy

Program, http://www.hhs.gov/ocio/securityprivacy/index.html. Information is

safeguarded in accordance with applicable laws, rules and policies, including the HHS

Information Technology Security Program Handbook, all pertinent National Institutes of

Standards and Technology (NIST) publications, and OMB Circular A-130, Management of Federal Resources. Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (user ID and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800-88.

RETENTION AND DISPOSAL: Records pertaining to recruitment and use of outside peer reviewers are destroyed three years after final action; they are retained longer if required for business use (see General Records Schedule (GRS) 1.2, Item 010, Grant and Cooperative Agreement Program Management Records). Records pertaining to recruitment and use of other outside individuals (e.g., experts, patient advocates, and members of mission-related non-FACA committees) are currently unscheduled.

Unscheduled records must be retained indefinitely pending the agency's submission, and NARA's approval, of a disposition schedule. HHS anticipates proposing to NARA, as an appropriate retention period for these records, "three years after final action, or longer if required for business use" (similar to the period provided in GRS 1.2, Item 010) or "when no longer needed for administrative purposes" (similar to the periods applicable to similar

records not retrieved by personal identifier which are not covered under this SORN; i.e.: N1-442-93-1, Item 37 for the Agency for Toxic Substances and Disease Registry's Curriculum Vitae Files, and NC1-235-82-1, Item 100-3 for the Office of the Secretary's Advisory Committee Candidate Resume Files).

SYSTEM MANAGER(S) AND ADDRESS(ES):

For CDC/NCHS Consultant Records:

Centers for Disease Control and Prevention (CDC), Director, National Center for Health Statistics,
 OPHSS, Prince George's Metro IV Bldg., Rm. 7209, MS P08, Centers for Disease Control and
 Prevention, 3311 Toledo Road, Hyattsville, MD 20782

For FDA Patient Representative Records:

Food and Drug Administration (FDA), Advisory Committee Oversight & Management Staff,
 10903 New Hampshire Avenue, Bldg. WO32, Rm. 5129, Silver Spring, MD 20993-002

For ACF Peer Reviewer Records:

Administration for Children and Families (ACF), Privacy Act Contact, Office of Information
 Systems, 330 C Street, N.W., Washington, DC 20201

For HRSA Peer Reviewer Records:

Health Resources and Services Administration (HRSA), Chief, Policy, Analysis & Training Branch,
 Division of Independent Review, Office of Federal Assistance Management, 5600 Fishers Lane,
 Rockville, MD 20857

For SAMHSA Peer Reviewer Records:

 Substance Abuse and Mental Health Services Administration (SAMHSA), Director, Division of Grant Review, 5600 Fishers lane, Rockville, MD 20852

For Other Consultant Records, Maintained by SAMHSA Contractors:

 Substance Abuse and Mental Health Services Administration (SAMHSA), Director, Division of Contracts Management, Office of Program Services, 5600 Fishers Lane, Rockville, MD 20852

NOTIFICATION PROCEDURE: An individual who wishes to know if this system contains records about him or her should submit a written request to the relevant System Manager indicated above. The individual must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE: An individual seeking access to records about him in this system should submit a request following the same procedure indicated under "Notification Procedure."

CONTESTING RECORD PROCEDURE: An individual seeking to amend the content of information about him or her in this system should contact the relevant System Manager indicated above and reasonably identify the record, specify the information contested, state the corrective action sought, and provide the reasons for the amendment, with supporting justification.

RECORD SOURCE CATEGORIES: Most information is obtained directly from the

individual record subject. Information pertaining to references and recommendations is obtained

from other private individuals, educational institutions, current and former employers, HHS

program personnel, biographical reference books, private organizations, Members of Congress,

and other government sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM: None

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